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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,673	02/23/2004	Conceicao Minetti	13564.105004	3568

65989 7590 05/29/2007

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EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	**PAPER NUMBER**
1645	
MAIL DATE	**DELIVERY MODE**
05/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,673	MINETTI ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-21 and 27-40* is/are pending in the application.

4a) Of the above claim(s) *27-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-21 and 31-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendments

1) Acknowledgment is made of Applicants' preliminary amendments filed 02/23/04 and 03/16/07.

Election

2) Acknowledgment is made of Applicants' election filed 12/26/06 in response to the restriction and species election requirements mailed 09/26/06. Applicants have elected, with traverse, invention I, claims 16-21 and 31, and the nucleic acid species of SEQ ID NO: 1 having a substitution at position 195, and the nucleotide substitution T-583 ->A.

With regard to the restriction requirement, Applicants' cite M.P.E.P § 803 and state that there are two criteria for a proper requirement for restriction between patentably distinct inventions: (a) The invention must be independent as claimed, and (b) There must be a serious burden if the restriction is not required. Applicants submit that all groups of the restricted claims are properly presented in the same application; undue diverse searching would not be required; and all claims should be examined together. Applicants allege that the Office has not shown that examination of all the pending claims would require undue searching and/or place a serious burden on the Office, which is a requisite showing for proper issuance of a restriction requirement. Applicants contend that a recombinant nucleic acid molecule encoding a modified pneumolysin and a method for obtaining the modified pneumolysin by expressing the recombinant nucleic acid molecule would not be unduly burdensome and may be searched together. Applicants state that there should not be a serious burden to search a molecule and a method of using the molecule. Applicants ask that inventions I and IV be examined together. Applicants state that, of the four groups of invention identified, two are in the same class 435 and that to search prior art in a single class cannot be deemed undue diverse searching. Applicants assert that at a minimum, inventions II and IV should also be examined together.

With regard to the species election requirement, Applicants' traversal is on the grounds that: (a) Applicants are entitled to prosecution of claims covering a reasonable number of species disclosed in an application in accordance with 37 C.F.R § 1.46; and (b) there would be no undue burden on the Office to conduct a substantive examination of the claims as related to the

embodiments disclosed in the instant application. Applicants state that the election of species requirement is improper and that the Office may require an election of species to not more than a reasonable number of species before taking further action in the application. Applicants further submit that according to M.P.E.P § 806.04, an allowable generic claim may link a reasonable number of species embraced thereby. Applicants' allege that the Office's position that 'one' is the maximum reasonable number of species is inconsistent with 37 C.F.R § 1.146 and the M.P.E.P. Applicants contend that the instant claims present a reasonable number of species embraced thereby and therefore are entitled to examination of all of the pending claims.

Upon further consideration, all species in claims 16 and 17 have been fully examined. The species election requirement set forth in the Office Action mailed 09/26/06 is hereby withdrawn.

Applicants' arguments with regard to the restriction requirement have been carefully considered, but are not persuasive for the following reasons. Contrary to Applicants' assertion, the Office has met the two criteria set forth in M.P.E.P § 803 for a proper requirement for restriction between patentably distinct inventions: (a) independent invention as claimed, and (b) a serious burden if the restriction is not required. The Office has shown that undue diverse and non-coextensive searching would be required since the products, i.e., antibodies, modified polypeptide, and mutated nucleic acid, used in the methods of inventions II, III and IV respectively differ from one another in their structure and function and belong to different classes and/or subclasses. In addition, there is also non-patent literature search burden and examination burden. With regard to inventions I and IV that are related as product and process of using the product, Applicants should note that as set forth in paragraph 4 of the Office Action mailed 09/26/06, where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or that otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. In the instant application, claim 30 would be retained as a pending withdrawn claim. For the reasons delineated above, the restriction requirement set forth in the instant application is maintained and is hereby made FINAL.

Status of Claims

3) Claims 1-15 and 22-26 have been canceled via the amendment filed 02/23/04.

Claims 16-18, 20, 21, 27 and 29-30 have been amended via the amendment filed 02/23/04.

New claim 31 has been added via the amendment filed 02/23/04.

Claims 16-19 and 31 have been amended via the amendment filed 03/16/07.

New claims 32-40 have been added via the amendment filed 03/16/07.

Claims 16-21 and 27-40 are pending.

Claims 27-30 have been withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Claims 16-21 and 31-40 are under examination. A First Action on the Merits is issued for these claims.

Information Disclosure Statement

4) Acknowledgment is made of Applicants' information disclosure statement filed 02/23/04. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Sequence Listing

5) The raw sequence listing submitted in this application has been entered on 02/23/04.

Priority

6) This application is a divisional application of SN 09/120,044, filed 07/21/1998, *now U.S. patent 6,764,686* and claims priority to provisional applications 60/073,456 and 60/053,306, filed 02/02/1998 and 07/21/1997 respectively.

Oath/Declaration

7) The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application, by application number and filing date is required. See M.P.E.P §§ 602.01 and 602.02.

Non-initialed alterations made to the address of Joseph Tai are objected to.

Specification

8) The instant specification is objected to for the following reason:

The first paragraph of the specification as amended via the amendment filed 02/23/04 does not accurately reflect current issued status of the prior non-provisional application as indicated above in italicized letters under the section 'Priority'.

Rejection(s) under 35 U.S.C. § 101

9) 35 U.S.C. § 101 states:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this cycle.

10) Claim 19 and those dependent therefrom, and claims 32-40 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

Claim 19, as written, does not sufficiently distinguish over a pneumococcus microorganism as it exists naturally comprising one or more spontaneous mutations in the recited nucleic acid sequence, because the claim does not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring product. The claimed microorganism is not an 'isolated microorganism'. Similarly, the 'molecule' claimed in claims 32-40 encompasses a non-isolated microorganism as it exists naturally as explained above. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980)*. The claim(s) should be amended to indicate the hand of the inventor, e.g., by insertion of --An isolated-- if support for such a limitation exists in the instant specification. See MPEP 2105.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

11) Claim 17 and those dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 17, as amended, includes the new limitations: 'A recombinant molecule comprising the pneumolysin nucleic acid sequence of SEQ ID NO: 1' or 'non-coding sequence changes thereof'. Applicants state that the support for the amendment can be found in page 33, line 30 to page 34, line 11 of the specification. However, this part of the specification does not provide descriptive support for the broadly recited 'recombinant molecule' comprising either the pneumolysin nucleic acid sequence of SEQ ID NO: 1, or non-coding sequence changes of the pneumolysin nucleic acid sequence of SEQ ID NO: 1, as claimed currently. The generic limitation 'recombinant molecule' encompasses a plethora of molecules including bacteria, viruses, fungi,

parasites, bacteriophages, vectors, plasmids, cosmids, human cells, animal cells and any molecule. Therefore, the above-identified limitation in claim 17 is considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed by pointing to specific lines and pages, for the new limitations, or alternatively, remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

12) Claims 32-40 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

New claims 32-40 include the limitation: 'A molecule encoding the nucleic acid sequence of modified pneumolysin polypeptide ....'. Applicants state that Figure 6 provides support for the new claims 32-40. However, Figure 6 is stated as describing the positions of the nucleic acid and amino acid substitutions in specific modified pneumolysin polypeptides pNVJ1, pNVJ45, pNVJ20, pNVJ22, pNVJ56, pNV103, pNV207, pNV111, and pNV211 as described at lines 4-7 of page 9 of the specification. This does not provide support for the broadly claimed 'molecule' encoding each of the recited nucleic acid sequence. The generic limitation 'molecule' encompasses a plethora of molecules including bacteria, viruses, fungi, parasites, bacteriophages, vectors, plasmids, cosmids, human cells, animal cells, and any molecule other than a nucleic acid. Figure 6 of the specification does not provide descriptive support for such a 'molecule' as claimed currently. Therefore, the above-identified limitation in the instant claims is considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed by pointing to specific lines and pages, for the new limitations, or alternatively, remove the

new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

13) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

14) Claims 16-21 and 31 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 16 is indefinite for lacking proper antecedent basis in the limitation 'wild-type pneumolysin' (see line 8). The earlier part of the claim at line 3 already includes the limitation 'a wild-type pneumolysin'. Does it mean that the 'wild-type pneumolysin' recited in line 8 of the claim is different from the one recited in line 3 of the claim?

(b) Claim 20 is indefinite and incorrect in the limitation: 'microorganism is .... mammalian and insect cells'. Mammalian and insect cells do not come under the category of microorganisms.

(c) Claim 17 is vague and confusing in the limitation 'non-coding sequence changes thereof', because it is unclear what precise changes are encompassed in this limitation.

(d) Claim 31 is indefinite because of the improper antecedent basis in the limitation: 'the vector'. Claim 31 depends from claim 16 or 17, which does not recite any 'vector'.

(e) Claim 16 is indefinite and incorrect in the limitation: 'said more than one amino acid substitution occurs' as opposed to the limitation --said more than one amino acid substitutions occur--.

(f) Claims 18-21 and 31, which depend directly or indirectly from claim 16 or 17, are also rejected as being indefinite, because of the indefiniteness identified above in the base claim.

Objection(s)

15) Claim 31 is objected to for the limitation 'of:' as opposed to the limitation --of--.

Remarks

16) Claims 16-21 and 31-40 stand rejected.

17) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

18) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

19) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

S. DEVI, PH.D.
PRIMARY EXAMINER

May, 2007